



Patent Docket P1363R1C1

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IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re Application of  Deborah Ann Ansaldi et al.  Serial No.: 10/642,409  Filed: August 15, 2003  For: SEPARATION OF POLYPEPTIDE MONOMERS	Group Art Unit: 1643  Examiner: Holleran, Anne L.  Confirmation No: 1482  CUSTOMER NO: 09157  <b>CERTIFICATE OF MAILING</b> I hereby certify that this correspondence is being deposited with the United States Postal Service with sufficient postage as first class mail in an envelope addressed to: Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450 on  December 19, 2006  <i>Pamela Gavette</i> Pamela Gavette
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**FOURTH SUPPLEMENTAL INFORMATION DISCLOSURE STATEMENT**

Mail Stop Amendment  
Commissioner for Patents  
P.O. Box 1450  
Alexandria, VA 22313-1450

Sir:

Applicants submit herewith patents, publications or other information (listed on the attached Form PTO-1449) of which they are aware, which they believe may be material to the examination of this application and in respect of which there may be a duty to disclose in accordance with 37 CFR §1.56.

This Information Disclosure Statement is filed in accordance with the provisions of:

☐ **37 CFR §1.97(b)**

- within three months of the filing date of the application other than a continued prosecution application under 37 CFR §1.53(d); **or**
- within three months of the date of entry of the national stage of a PCT application as set forth in 37 CFR §1.491, **or**
- before the mailing of the first Office action on the merits; **or**
- before the mailing of the first Office action after the filing of a request for a continued examination under 37 CFR §1.114.

☒ **37 CFR §1.97(c)**

- by the applicant after the period specified in 37 CFR §1.97(b), but prior to the mailing date of any of a final action under 37 CFR §1.113, or a notice of allowance under 37 CFR §1.311, or an action that otherwise closes prosecution in the application, and is accompanied by either the fee set

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forth in 37 CFR §1.17(p) **or** a statement as specified in 37 CFR §1.97(e), as checked below.

☐ **37 CFR §1.97(d)**

- after the period specified in CFR §1.97(c), and is accompanied by the fee set forth in 37 CFR §1.17(p) **and** a statement as specified in 37 CFR §1.97(e), as checked below.

[If either of boxes 37 CFR §1.97(c) or 37 CFR §1.97(d) is checked above, the following statement under 37 CFR §1.97(e) may need to be completed.]

- ☐ **37 CFR §1.97(e)** Each item of information contained in the information disclosure statement was first cited in any communication from a foreign patent office in a counterpart foreign application not more than three months prior to the filing of this information disclosure statement.
- ☐ **37 CFR §1.704(d)** Each item of information contained in the information disclosure statement was cited in a communication from a foreign patent office in a counterpart foreign application and the communication was not received by any individual designated in §1.56(c) more than thirty days prior to the filing of this information disclosure statement. Therefore, in accordance with the provisions of 37 CFR §1.704(d), the filing of this information disclosure statement will not be considered a failure to engage in reasonable efforts to conclude prosecution under 37 CFR §1.704.
- ☒ The U.S. Patent and Trademark Office is hereby authorized to charge Deposit Account No. 07-0630 in the amount of \$180.00 to cover the cost of this Information Disclosure Statement under 37 CFR §1.17(p). Any deficiency or overpayment should be charged or credited to this deposit account.

A list of the patent(s) and/or publication(s) is set forth on the attached Form PTO-1449. Copies of the items listed on the PTO-1449 form are supplied herewith, except for U.S. patent(s) and U.S. patent application publication(s). Copies of U.S. patents and patent application publications will not be supplied unless requested by the Office [37 CFR '1.98(a)(2)(ii)]. See Final Rule **1287 OG** (October 12, 2004).

A concise explanation of relevance of the items listed on PTO-1449 is:

- ☐ not given
- ☐ given for each listed item
- ☒ given for only non-English language listed item(s) [Required]
- ☐ in the form of an English language copy of a Search Report from a foreign patent office, issued in a counterpart application, which refers to the relevant portions of the references.

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In accordance with 37 CFR §1.97(g), the filing of this information disclosure statement shall not be construed as a representation that a search has been made.

In accordance with 37 CFR §1.97(h), the filing of this information disclosure statement shall not be construed to be an admission that the information cited in the statement is, or is considered to be, material to patentability as defined in 37 CFR § 1.56(b).

The Commissioner is hereby authorized to charge any additional fees required under 37 CFR 1.16 and 1.17 for this Information Disclosure Statement, or credit overpayment to Deposit Account No. 07-0630. A duplicate copy of this sheet is enclosed.

Respectfully submitted,

GENENTECH, INC.

Date: December 18, 2006

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FORM PTO-1449

U.S. Dept. of Commerce  
Patent and Trademark OfficeAtty Docket No.  
P1363R1C1Serial No.  
10/642,409

## LIST OF DISCLOSURES CITED BY APPLICANT

(Use several sheets if necessary)

Applicant  
Ansaldi et al.Filing Date  
15 Aug 2003Group  
1643

## U.S. PATENT DOCUMENTS

Examiner Initials		Document Number	Date	Name	Class	Subclass	Filing Date
	39	4,136,094		Condie			
	40	4,639,513		Hou et al.			
	41	4,736,020		Hillen et al.			
	42	5,064,943	12.11.91	McCoy et al.			
	43	5,106,832	21.04.92	Froesch et al.			
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Examiner Initials		Document Number	Date	Country	Class	Subclass	Translation Yes No
	45	91328/82		AU			
	46	1128418	27.07.82	CA			
	47	373325		EP			
	48	1-226827		JP (W/ENGLISH ABSTRACT)			
	49	2-222697		JP (W/ENGLISH ABSTRACT)			
	50	7-285885	31.10.95	JP (PARTIAL OR FULL ENGLISH TRANSL)			
	51	86/06727		WO			
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	53	91/18621		WO			
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## OTHER DISCLOSURES (Including Author, Title, Date, Pertinent Pages, etc.)

	57	Alberts et al. <u>Molecular Biology of the Cell</u> pps. 121-122 (1983)
	58	Aoyama and Chiba J. <u>Immunol. Methods</u> 162:201-210 (1993)
	59	Bruck et al., "Purification of mouse monoclonal antibodies from ascitic fluid by DEAE Affi-Gel Blue chromatography" <u>Methods in Enzymology</u> 121:587-596 (1986)
	60	Coleman et al. <u>Journal of Biological Chemistry</u> 270(23):13842-13849 (1995)
	61	Crimmins, "Analysis of Disulfide-Linked Homo-and hetero-Peptide Dimers with a Strong Cation-Exchange Sulfoethyl Aspartamide Column" <u>Peptide Research</u> 2(6):395-401 (1989)
	62	Database WPI Week 9601 <u>AN 96-006908 &amp; JP 07 285885 A</u> (English abstract of Reference 34 hereof), London:Derwent Publications Ltd.
	63	Duffy et al. <u>Biopharma</u> pps. 34-44, 47 (1989)
	64	Gemski et al. <u>Biotechniques</u> 3(5):378-384 (1985)

Examiner

Date Considered

\*Examiner: Initial if reference considered, whether or not citation is in conformance with MPEP 609; draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant.

FORM PTO-1449  <b>LIST OF DISCLOSURES CITED BY APPLICANT</b> (Use several sheets if necessary)		U.S. Dept. of Commerce Patent and Trademark Office		Atty Docket No. P1363R1C1	Serial No. 10/642,409
				Applicant Ansaldi et al.	
				Filing Date 15 Aug 2003	Group 1643
<b>OTHER DISCLOSURES (Including Author, Title, Date, Pertinent Pages, etc.)</b>					
65	Graf et al., "Ion exchange resins for the purification of monoclonal antibodies from animal cell culture" <u>Bioseparation</u> 4(1):7-20 (Feb 1994)				
66	Gupta et al., "Protein Aggregation kinetics: Applications to protein A chromatography" <u>CAPLUS, Bibliography &amp; Abstract</u> , fur: (Abstract Nr. 2003:179302; Paper abstract ACS National meeting, new Orleans, LA, U.S.A.) (March 23-27 2003)				
67	Haase-Pettingell and King <u>Journal of Biological Chemistry</u> 263(10):4977-4983 (1988)				
68	Higo et al., "Model study of 2-dim. protein aggregates in the nucleation stage of crystallization" <u>J. Chem. Phys.</u> 99:9156-9162 (1993)				
69	Lewin <u>Genes IV</u> pps. 14 (1990)				
70	Mateu and Fersht <u>EMBO J.</u> 17(10):2748-2758 (1998)				
71	Noeva et al., "Antigenicity of Aggregated Immunoglobulins in Gamma Globulin Preparations" <u>Comptes rendus de l'Academie bulgare des Sciences</u> 27(9):1291-1294 (1974)				
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73	Patro et al., "Simulations of Reversible Protein Aggregate and Crystal Structure" <u>Biophysical J.</u> 70:2888-2902 (1996)				
74	"Pilot-scale capture of monoclonal antibody IgG4 on MabSelect Xtra with high purity and yield" <a href="http://www.bioprocess.amershambiosciences.com">www.bioprocess.amershambiosciences.com</a> ( <a href="http://Applic%5Cup00738.nsf/va-temp/A8646CBD2D6F0539C1256F6A0054B7B9/\$file/11001158AA.pdf">/Applic%5Cup00738.nsf/va-temp/A8646CBD2D6F0539C1256F6A0054B7B9/\$file/11001158AA.pdf</a> ), Amersham				
75	<u>Protein Purification Methods, a practical approach</u> (ISBN: 0 19 963003 8), Harris ELV and Angal S., Oxford University Press pps. 175-244 (1995)				
76	<u>Scopes Protein Purification: Principles and Practice</u> , Charles Cantor, 2nd edition, New York:Springer-Verlag, Chapter 5, (1987)				
77	"Sephadex G-25 media and pre-packed columns" <u>Data File/Amersham Biosciences</u> pps. S.1-7				
78	Tankersley D.L. et al. <u>Mol. Immuno.</u> 25(1):41-48 (1988)				
79	Teeling et al., "Therapeutic efficacy of intravenous immunoglobulin preparations depends on the immunoglobulin G dimers: studies in experimental thrombocytopenia" <u>Immunobiology</u> 98(4):1095-1099 (2001)				
80	Voet, Donald und Judith G. <u>Biochemistry</u> , John Wiley & Sons, Inc. pps. 1099-1100 (1990)				
81	Whitlow et al., "Multivalent Fvs: characterization of single-chain Fv oligomers and preparation of bispecific Fv" <u>Protein Engineering</u> 7(8):1017-1026 (1994)				
82	<a href="http://www.lgcpromochem-atcc.com/searchCatalogs">www.lgcpromochem-atcc.com/searchCatalogs</a> (2 pages of on-line catalog entry for 266 cell line ATCC Nr. TIB-196)				
Examiner				Date Considered	
*Examiner: Initial if reference considered, whether or not citation is in conformance with MPEP 609; draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant.					